DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

July 24, 1997

97-PHI-36

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 7/29/97
Reviewed by: Karyn M Campbell

Gary E. West, Owner/Executive Director
Valley National Gases, Inc.
67 43rd Street
Wheeling, WV 26003-7061

Dear Mr. West:

On June 12, 23-24, and 26, 1997, Philadelphia District Investigator Cynthia L. Rakestraw conducted an inspection of your medical oxygen manufacturing facility located at 318 Mahoning Avenue, New Castle, PA. The medical oxygen filled by this facility is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act and, as such, is subject to the requirements of *Title 21 Code of Federal Regulations* (21 CFR).

At the conclusion of the inspection, Investigator Rakestraw issued form FDA 483, Inspectional Observations, to Martin Taub, Jr., Customer Service Manager, and discussed the observations with him. A copy of the FDA 483 is enclosed for your information. This inspection revealed that medical oxygen manufactured by the New Castle, PA facility is adulterated within the meaning of Section 501(a)(2)(B) of the FD&C Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Parts 210 and 211, as indicated below:

1. Failure to assay truck-mounted cryogenic vessels for identity and strength prior to release [21 CFR 211.165(a)].

The inspection revealed that, prior to Investigator Rakestraw's initial visit on June 12, 1997, the New Castle, PA facility was testing oxygen only from the 2500 gallon storage tank from which customers' truck-mounted vessels are filled. Since these types of vessels usually contain residuals from prior fills, the new lot of oxygen filled into these vessels becomes co-mingled with the residuals -- producing a new batch of oxygen which requires testing and a new lot number.

2. Failure to prepare batch production records for each batch of medical oxygen produced [21 CFR 211.188].

Investigator Rakestraw observed that, in the month of June 1997 alone, the New Castle, PA facility failed to complete packaging control records for [redacted] of the [redacted] fills completed as of June 20, 1997.

3. Failure to maintain complete records of the calibration of the [redacted] oxygen analyzer [21 CFR 211.194(d)].

As referenced in item 2 above, Investigator Rakestraw observed that packaging control records, on which information regarding the [redacted] calibration is recorded, are not always completed for every lot of liquid oxygen filled.

4. Failure to follow written procedures regarding the appropriate documentation of the completion of each step in the liquid oxygen manufacturing process, and failure to document the execution of liquid oxygen manufacturing operations at the time of performance [21 CFR 211.100(b)].

In addition, the inspection revealed that the New Castle, PA facility distributes compressed oxygen cylinders filled by its sister facility in Cranberry, PA which also provides the New Castle, PA site with Certificates of Analysis (CoA) for these cylinders. Investigator Rakestraw observed that the New Castle, PA facility has on file "blank" CoA's that appear to be preprinted with results from identification, odor, and assay tests. She reviewed [redacted] CoA's and noticed that [redacted] of these appear to be copies of the "blank" CoA's annotated with the pertinent lot numbers and dates. When comparing results recorded on the actual filling records for the lots involved in these [redacted] CoA's, Investigator Rakestraw noticed that [redacted] show a slightly different assay result [redacted] It is not clear which Valley National Gases site -- New Castle, PA or Cranberry, PA -- is responsible for preprinting the results Investigator Rakestraw observed on the "blank" CoA's; however, laboratory records are required to contain accurate information with respect to the results of analyses associated with a specific lot of product. Consequently, if the Cranberry, PA site is filling and testing the compressed oxygen cylinders it supplies to the New Castle, PA site and is providing the New Castle, PA site with CoA's, then those CoA's must be lot specific and must include the actual testing results associated with the specific lot.

We acknowledge the fact that Mr. Taub instituted steps to correct some of the observations before the inspection was concluded and that, during the discussion of the FDA 483 observations, Mr. Taub told Investigator Rakestraw that all of the deficiencies will be

corrected. To assist your company in this endeavor, we are also enclosing a copy of "Fresh Air '97: A Look at FDA's Medical Gas Requirements." We recommend that you take into consideration the deficiencies listed in this Warning Letter and proactively evaluate the compliance status of all Valley National Gases sites engaged in the manufacture and distribution of medical gases.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to assure that all of your company's operations are in compliance with the Act and its associated regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be directed to the attention of Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,

Diana J. Kolaitis
District Director

Enclosures

cc: Martin Taub, Jr., Customer Service Manager
Valley National Gases, Inc.
318 Mahoning Avenue
New Castle, PA 16102

Robert E. Bastian, Director
Division of Primary Care and Home Health Services
PA Department of Health
132 Kline Plaza, Suite A